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IN THE UNITED STATES SUPREME COURT

MARK MILLER AND CHERYL MILLER, INDIVIDUALLY AND MARK MILLER, AS ADMINISTRATOR OF THE ESTATE OF MATTHEW MILLER, DECEASED,

Petitioners,

v.

PFIZER, INC. (ROERIG DIVISION),

Respondent.

ON PETITION FOR WRIT OF CERTIORARI FOR THE UNITED STATES COURT OF APPEALS FOR THE TENTH CIRCUIT

PETITION FOR WRIT OF CERTIORARI

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QUESTIONS PRESENTED FOR REVIEW

1. What standards should a district court employ when it appoints independent experts or technical advisers to assist in its "gatekeeping" responsibilities, and specifically, is it an abuse of discretion to deprive the court's own experts of the most current and available scientific information?

2. Whether the courts below erred by ignoring the on-going, developing scientific evidence linking Zoloft to suicide, and, specifically whether the FDA's March 22, 2004, pronouncement that Pfizer should warn about the potential association between Zoloft and suicide merits either an outright reversal or GVR?

Certificate of Interested Persons

The undersigned counsel of record certifies that the following listed parties have an interest in the outcome of this case. These representations are made in order that the Justices of this Court may evaluate possible disqualification or recusal.

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REPORTS OF OPINIONS

The district court entered numerous interlocutory opinions or orders in this case, some of which are published online on Westlaw and/or LEXIS. The first was its November 10, 1999 order denying Pfizer's motion to either strike the complaint or permit Pfizer to file a general denial. It is published at *Miller v. Pfizer, Inc.*, 1999 WL 1063046 and 1999 U.S.Dist. LEXIS 18345 (D.Kan. 1999).

Other orders are unpublished, like the district court's June 27, 2000, order refusing on First Amendment grounds to "gag" the Millers and preclude them from speaking out publically about the association between Zoloft and suicide. Further, its June 12, 2000 order denied Pfizer's motion to strike semi-final witness list or, the alternative, to strike witnesses whose testimony is not described, and decrying said motion as a tactic which "degrades the legal profession and the practice of law."

Orders specifically at issue in this Petition, include the district court's August 18, 2000, Order to Show Cause why independent experts should not be appointed, which is published at 2000 U.S. Dist. LEXIS 20640 (Note: dated December 2000 in LEXIS), and its April 24, 2001, Order Appointing Independent Experts, which is apparently unpublished. Because of the importance of these two Orders to the issues raised by this Petition, see App. 9-10.

The two opinions which lead to summary judgment for Pfizer are published at *Miller v. Pfizer, Inc.* 196 F.Supp.2d 1062 (D. Kan. 2002), and *Miller v. Pfizer, Inc.* 196 F.Supp.2d 1095 (D. Kan. 2002). App. at 1-2. The Tenth Circuit's opinion affirming the summary judgment for Pfizer is published at *Miller v. Pfizer*, 356 F.3d 1326 (10th Cir. 2004). App. at 3.

GROUNDS FOR JURISDICTION OF THE UNITED STATES SUPREME COURT

The United States Court of Appeals for the Tenth Circuit delivered its opinion on February 4, 2004. This Court has discretionary jurisdiction pursuant to 28 U.S.C. §1254(1).

STATEMENT OF THE CASE

This Kansas diversity jurisdiction case involves the tragic death by suicidal hanging of Matthew Miller, a 13-year old boy. In July 1997, seven days before his death, a doctor who, unbeknownst to the boy's parents, was paid by Pfizer to give speeches hawking Zoloft, prescribed the SSRI drug Zoloft for Matt.

The legal case involves the preclusion of testimony from Dr. David Healy, the world's foremost expert on the issue of antidepressant-induced suicidality. Dr. Healy has passed every other *Daubert* challenge in federal cases around the country on this same issue. Indeed, this expert has testified before, or provided information directly to, regulators in both the United Kingdom and the United States on the SSRI/suicidality issue. Both countries have, thereafter, required warnings to be issued about an association between the SSRIs and suicide. Specifically, and most recently, on March 22, 2004, consistent with Dr. Healy's research and testimony, the FDA recommended that Pfizer include a "warning" in the Zoloft label, alerting doctors and patients that they should watch closely for "the emergence of suicidality." App. at 5-6.

Zoloft is a psychoactive, antidepressant drug in the Selective Serotonin Reuptake Inhibitor [SSRI] class. The other two most well-known drugs in this class are Prozac and Paxil.

The scientific evidence linking these drugs with an increased risk of suicide, particularly for children and adolescents, has been mounting for years. Developments within the last year before the decision of the Tenth Circuit include June 2003 announcements by the British Medicines Control Agency (MCA) and U.S. Food and Drug Administration (FDA) that Paxil may pose an increased risk of suicide for children and adolescents; and an August 22, 2003, announcement by the maker of the similar drug Effexor, warning that it, too, increases

the risk of suicide for children and adolescents. Specific to Zoloft, in December 2003 the British MCA "contraindicated" Zoloft for children and adolescents, finding that the data regarding Zoloft "show a consistently higher incidence of suicidal thoughts and self-harm in children and adolescents" and that "the commonest reason for discontinuation of treatment was suicidal thoughts/self-harm." The Millers asked the Tenth Circuit to take judicial notice of these on-going developments, but the court denied the requests.

On Monday, February 2, 2004 – two days before the Tenth Circuit's affirmance in this case – two advisory panels of the FDA heard evidence from over 60 witnesses concerning the link between SSRI drugs and increased suicidality in children and adolescents. Later that evening, the panels took the extraordinary step of issuing their own warnings to "put a speed bump in the road" regarding the use of this class of medications in children and adolescents, once again, in large measure, because of the risk of suicide. *See* FDA.Advisory Committee, *Antidepressants Strengthen Warnings About Pediatric Suicidality Risk Needed Immediately, Cmte. Says*, <http://fdaadvisorycommittee.com/FDC/AdvisoryCommittee/Committees/Anti-Infective+Drugs/020204_Suicide/020204_SuicideR.htm> (Feb. 2, 2004). App. at 5-6.

Then, finally, as noted above, on March 22, 2004, the FDA itself issued a Public Health Advisory, recommending that all of the manufacturers of these drugs, including Pfizer, "include in their labeling a Warning statement that recommends close observation ... [for] the emergence of suicidality." *See* FDA Public Health Advisory, *Subject: Worsening Depression and Suicidality in Patients Being Treated with Antidepressant Medications*, <http://www.fda.gov/cder/drug/antidepressants/AntidepressantsPHA.htm> (March 22, 2004). App. at 5-6. As with the prior continuing scientific and regulatory developments, these matters

are appropriate for judicial notice by this Court. Rule 201(f), Fed.R.Ev.

The saga continues to unfold. In the wake of the FDA's ruling, information has emerged indicating that the FDA itself muzzled its own medical review officer, who intended to tell the February 2004 panels that his review of the companies' own data disclosed an increased risk of suicide, and that, in turn, has prompted two congressional investigations into the concealment of this problem from the public eye. *See* Joe Barton, *Barton, Greenwood Seek Info From FDA on Antidepressants*, <http://energycommerce.house.gov/108/Letters/0324204_1242print.htm> (March 24, 2004). App. at 7.

Realizing that the District of Kansas' local rules provide for a four-month discovery period, and anticipating the Defendant's *de rigeur Daubert* motion to exclude the testimony of Plaintiffs' principal causation expert, Dr. David Healy (a highly credentialed Irish neuro-psychopharmacologist with extensive peer-reviewed publications on point), prior to the initial Rule 16 conference in November 1999, the Millers provided a preliminary disclosure report from Dr. Healy and requested that the district court appoint independent experts to help evaluate the scientific reliability of the opinion testimony from **both** parties. The Millers expected that early appointment of such experts would allow full discovery, discussion and rebuttal of the scientific arguments of both sides so that the independent experts could have access to all of the pertinent information and could properly advise the court concerning scientific reliability, based on a fully-developed record, tailored towards their questions.

In all honesty, they also expected that careful scrutiny of **both** parties' experts would reveal the hypocrisy in the drug manufacturer's "scientific" arguments and demonstrate that, if any expert's opinion failed *Daubert* muster it would be that of Pfizer's principal expert, Dr. J. John Mann of Columbia

University. Specifically, they knew that Dr. Mann's only **peer-reviewed** publications began with a lamentation about iatragenic suicide and included statements of concern about the "small vulnerable sub-population" of patients who might be at risk for increased suicidality as a result of these drugs. Dr. Mann also advocated warnings about this risk. Mann & Kapur, *The Emergence of Suicidal Ideation and Behavior During Antidepressant Pharmacotherapy,* Arch. Gen. Psychiatry, 48: 1027 (1991).

They also knew that the hypothesis of a causal relationship between SSRI drugs and suicidality was **testable**, and that Dr. Mann's article articulated four different ways to test prospectively. *Id.* In addition, they also knew that neither Pfizer nor any other SSRI manufacturer had conducted such tests.

Plaintiffs knew as well that one causal chain, SSRI drugs trigger akathisia which, in turn, increase the risk of suicide *i.e.*, was not only acknowledged in both peer-review articles and sworn testimony by Dr. Mann, but was also rapidly becoming **generally accepted**. *See* AMERICAN PSYCHIATRIC ASSOC., DIAGNOSTIC AND STATISTICAL MANUAL OF MENTAL DISORDERS, DSM-IV-TR, §333.99, which effectively codifies this causal chain. App. at 8. This standard reference text was subsequently cited by federal Judge Donetta Ambrose in her May 30, 2002 Opinion rejecting a *Daubert* challenge to Dr. Healy in *Cassidy v. Eli Lilly*, Civil Action 821, U.S.D.C. (W.D.Pa. May 30, 2002, Ambrose, C.J.). Judge Ambrose synopsized succinctly that Dr. Healy's "theory," *i.e.*, that SSRI drugs trigger suicidality in a small subpopulation of patients "has attended **general acceptance** in the relevant scientific community." *Id.* at p. 10.

Unfettered scientific inquiry by truly independent, "neutral" and objective experts would disclose all of these things.

Unfortunately, although the issue was raised at the initial Rule 16 scheduling conference, the district court did not rule on the Millers' motion until 18 months later. By that time, the discovery deadline had passed, Dr. Healy had been deposed, Pfizer had challenged his testimony based on a number of arguments, some of which ultimately turned out to be totally ill-founded, and the district court below had raised several extra-*Daubert* questions of its own as to which it wanted independent advice. Even more unfortunate was the district court's subsequent decision to subjugate the wording of Rule 703 and the interests of justice to a mechanistic application of Rule 26 and judicial expediency.

As a consequence, the district court refused to allow Plaintiffs' counsel to provide the independent experts with all of the incriminating internal documents – hidden from public scrutiny via the court's own "protective order – and to allow Dr. Healy or Plaintiffs' counsel to address concerns raised by the court's independent experts. In this regard, the court itself became an unwitting accomplice in the concealment which is even at the current time under congressional investigation. The independent experts' frustration regarding the limited information available to them is perhaps best illustrated by the following colloquy which occurred during the *Daubert* hearing:

DR. DAVIS: ... I think it's pretty clear that Dr. Healy is a distinguished clinician and has many publications so that he would meet that type of criteria. . . . And it may be an evolving field and that, so there is a matter of judgment. . . . And what I anticipated when I came today that Dr. Healy might present his calculations or there might be a lot of discussions of the techniques of the calculations. . . .

THE COURT: Maybe I can shed some light on this, especially in regard to your comment that you may be

> expected to hear some more full explanation of where the 2.19 figure was derived. This is part of where the intersection of law and science is maybe not clear to somebody coming in from the outside. But under our federal rules which govern pretrial proceedings, each side obviously has a chance to call their own experts who will testify, and there's a time set as part of the discovery process where each expert is required to produce a written report that states all of the opinions that that expert will offer at the trial, and also the basis for the opinions. That has to be done by a certain time prior to trial. . . . So that's why, that's what my ruling was earlier, and that's why you haven't heard the Power Point presentation that was alluded to earlier.

App. at 00579-00614, Doc. No. 552, Transcript of Proceedings, November 20, 2001, P.M. session, filed 11/30/00, at 389-92.

Based on the uninformed opinions and unanswered concerns of the independent experts, and totally ignoring corroborating evidence, like the **UN**published May 1996 admission by Pfizer in a report to the FDA that Zoloft had, indeed, triggered the suicidal attempt of one young patient, the district court became the first court in the nation to exclude the testimony of Dr. Healy, on matters squarely within his specialty. Her decision in this regard is in conflict with several other reported and unreported district court opinions.

Summary judgment for Pfizer necessarily followed and the Tenth Circuit affirmed.

Interestingly, the district court's decision in this regard was handed down more than eight months after the verdict and judgment in another SSRI wrongful death case. In *Tobin v. SmithKline Beecham Pharms.*, 164 F.Supp.2d 1278 (D.Wy.

2001), appeal dism'd pursuant to settlement, (10th Cir. 2002), the jury found that "Paxil can cause some people to become homicidal and/or suicidal." Plaintiffs' expert in that case was the same Dr. Healy excluded by the district court in this case, and SmithKline Beecham's expert was the same Dr. Mann who had been designated by Pfizer to testify in the district court in this case. In its published post-trial opinion, as well as in an earlier pretrial ruling, the *Tobin* court rejected *Daubert* challenges to Dr. Healy's general and specific causation opinions.

ARGUMENT

> ***The search is not a search for scientific precision. We cannot hope to investigate all the subtleties that characterize good scientific work. . . . Furthermore, science itself may be highly uncertain and controversial with respect to many of the matters that come before the courts. . . . The law must be fair. One important procedural safeguard . . . is the right to a trial by jury. Any effort to bring better science into the courtroom must respect the jury's constitutionally specified role.***[1]

Pfizer's response to this Petition is easy to anticipate: "the case involves a discretionary ruling by a district judge and the petition emphasizes events which occurred after that ruling and were, therefore, not before the judge at the time."

Although there is a certain ineluctable facial appeal to this view, the circumstances of this case present the classic confrontation between *Fairness* and *Finality*. Courts at all

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[1] Breyer, Introduction, REFERENCE MANUAL ON SCIENTIFIC EVIDENCE (2nd ed., 2000)[hereinafter "REFERENCE MANUAL."]

levels in the judicial process must balance these oft-times competing considerations, but must necessarily do so in a manner that is consistent with the ultimate paradigm of Rule 1, Fed.R.Civ.P., to do what is "just." Or, as Justice Breyer stated in the REFERENCE MANUAL, "the law must be fair." *Id.* at 4.

Judges sometimes differ about those circumstances in which finality must yield to fairness. But the Justices of this Court have recently expressed unanimity in their opinion that "intervening developments" of a significant nature merit reconsideration in light of the most current information. *Lawrence v. Chater*, 516 U.S. 163 (1996)(granting summary GVR pursuant to 28 U.S.C. §2106 so that lower courts can consider implications of new position by a federal agency). The FDA's March 22, 2004, warnings edict places the case at bar squarely within the holding and rationale of *Lawrence*. App. 5-6.

No decision ever rendered by this Court has spawned more litigation in the lower courts or more citations in appellate opinions than *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579 (1993). A *Daubert*-based exclusionary motion is *de rigeur* tactics in every pharmaceutical case, no matter how strong the opinion evidence may be or how the expert himself is qualified. Indeed, numerous speakers at CLE functions have opined that defense counsel's failure to file such a motion may well subject him to claims of malpractice. This, in turn, puts a horrendous burden on the courts and on other litigants, particularly in a jurisdiction like Kansas where artificial caps on certain categories of damages enable wealthy defendants to literally spend plaintiffs like the Millers totally out of any meaningful judicial remedy.

There are some arenas in which the scientific evidence is developing. This case presents just such an arena. At the time this suit was initially filed, the published scientific literature directly on point was not terribly extensive. Much of

it, including Pfizer expert Dr. Mann's own article cited *supra*, and a 2000 article by Donovan and colleagues (which found that Zoloft had a relative risk of "deliberate self-harm" which was 4.4x higher than the index drug and did so with a *Daubert* "rate of error, *i.e.*, a "p-value" of .001) was supportive of the plaintiff's case.[2] But the issues were still being debated in many circles. More importantly, due to the pharmaceutical companies' failure to test the most pertinent information possible was non-existent. Additionally, the most damning evidence against Zoloft and its sister drugs was **unpublished**.[3] The scientific world is, indeed, only just now beginning to realize that the truly incriminating evidence regarding SSRI-induced suicidality has been withheld from public scrutiny. *See e.g., Data from Unpublished Trials Suggest that Most SSRI Antidepressant Drugs Unsuitable for Children*, LANCET (April 24, 2004)("The story of research into SSRI use in childhood depression is one of confusion, manipulation, and institutional failure.")[4]

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[2] *See* Stuart Donovan et al., *Deliberate self-harm and antidepressant drugs: Investigation of a possible link*, 177 Brit. J. Psychiatry 551-556 (2000).

[3] Not only has Pfizer refused to publish all of its data relating to Zoloft and suicide, it has also done everything within its power to deprive the public of access to this information and thereby conceal the danger. For example, even after it neglected to mark the critical May 1996 admission document discussed herein as "confidential," it tried like crazy to retrieve it and put it under wraps. As noted above, it also tried to "gag" the Millers and their counsel. And, most ironically, it actually succeeded in depriving the court's own experts of the most damning internal documentation of this lethal side effect.

[4] Craig J. Whittington, et al., *Selective Serotonin reuptake inhibitors in childhood depression: systematic review of published versus unpublished data*, 363 The Lancet 9418 (April 24, 2004) <http://www.thelancet.com/journal/vol363/iss9418/full/llan.363.9418.original_research.293>.

The FDA itself has exemplified the "institutional failure" of which the LANCET speaks. In May 1996, Pfizer filed a document reviewing incidents of suicidality in children and adolescents taking Zoloft. This was 14 months before Matt Miller's death. And, yet, the FDA ignored this damning admission and other evidence of incipient dangers for nearly seven years. Even in 2004, when public pressure forced it to schedule hearings, it muzzled its own chief scientific reviewer who had planned to sound a public alarm about SSRI-induced suicidality. This "institutional failure" has now even precipitated a congressional investigation into the concealment of the problem. *See* Joe Barton, *Barton, Greenwood Seek Info From FDA on Antidepressants*, <http://energycommerce.house.gov/108/Letters/0324204_1242print.htm> (March 24, 2004). App. at 7.

What do these matters have to do with the case at bar? Simply this. The district court below totally ignored Pfizer's admission that Zoloft had triggered a suicide attempt of one minor patient. This critical admission corroborated Dr. Healy's opinion on general causation. The evidence in the court below also demonstrated without question and even without the subsequent developments that Dr. Healy's opinion passes muster under both *Daubert* and *Kumho Tire Co. v. Carmichael*, 526 U.S. 137 (1999). Significantly, by "freezing the record" and specifically striking an exhibit which would summarize Pfizer's internal admissions, the district court also deprived its own experts of critical information.

The threshold question is, of course, "is this case *cert.*-worthy"? In the last decade this Court has written three major opinions concerning the district court's "gatekeeping" role under Rules 702-03. The first was, of course, *Daubert* itself. The Court took *cert.* in that case " in light of sharp divisions among the courts regarding the proper standard for the admission of expert testimony." *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 585 (1993). As noted above, there are "sharp

divisions" between the district court below on the one hand and at least four other district courts across the land regarding the admissibility of Dr. Healy's opinions on SSRI-induced suicidality.

Four years later the Court decided *General Elec. Co. v. Joiner*, 522 U.S. 136 (1997). In this instance *cert.* was granted, not to resolve a conflict in the lower courts, but rather "to determine what standard an appellate court should apply in reviewing" a *Daubert* decision. *Id.* at 138-39.

Finally in *Kumho*, *cert.* was granted "in light of uncertainty among the lower courts about whether, or how, *Daubert* applies to expert testimony that might be characterized as based not upon 'scientific' knowledge, but rather upon 'technical' or 'other specialized' knowledge." 526 U.S. at 146-47.

Thus, this Court exercised discretionary jurisdiction in all three cases to provide guidance to the lowers courts on how to decide and review critical decisions regarding expert testimony. From that perspective, this case cries out for *certiorari*.

Five years have passed since the Court's last writing on this important topic, and as this case itself amply illustrates, the courts below continue to flounder. Uncertainty is still rampart, and the lower courts continue to need guidance. Moreover, although the case law concerning independent experts is sparse, it is clear that there is a **conflict** between the way that the courts are handling such experts. For example, compare the case at bar, in which the experts' were hamstrung by very limited access to information with the extensive scientific inquiry in *Hall v. Baxter Healthcare Corp.*, 947 F.Supp. 1387 (D.Or. 1996). Specifically, in that case Judge Jones allowed the independent experts (whom he appointed pursuant to Rule 104 rather than Rule 706), (a) to review "voluminous" materials

submitted by both parties (apparently with no restrictions or censorship by the court), and (b) to hear the testimony of **both sides'** experts in each field. *Id.* at 1394. Moreover, because the hearing was conducted under Rule 104, Judge Jones permitted no evidentiary objections. *Id.* This is in stark contrast to Judge Vratil's numerous rulings in the *Daubert* hearing in the case at bar, at which she precluded Dr. Healy from providing answers to questions by the experts themselves and information within his knowledge and possession.

The case at bar presents a proper and timely forum for providing guidance regarding independent scientific experts, whether they are appointed pursuant to Rule 104, Rule 706, or some other authority. The "interim developments" merely ice the cake and underscore the true justness of the Millers' plight.

Justice should be based on the best available science. However, if the juridical history of *Daubert* itself illustrates nothing, it should tell both the Bench and the Bar that scientific orthodoxy is **not** the standard. The pharmaceutical industry argued for litmus tests. General acceptance. Or, if not that, peer review. But this Court rejected their arguments. Merrell Dow lost *Daubert*!

The law must accommodate developing scientific evidence, particularly where, as here, much of the most important information on point is withheld by industry from public scrutiny.

Many people have suggested that independently appointed scientific experts or technical advisers can help courts to sort the wheat from the chaff. Indeed, Justice Breyer's separate opinion in *Joiner* encouraged lower courts and litigants to use such resources. His subsequent introduction to the Second Edition of the REFERENCE MANUAL echoed those recommendations and emphasized that, properly used, this procedure should be "neutral, in principle favoring neither

plaintiffs nor defendants." *Supra* at p.7. If it is, then courts, litigants, and the scientific community itself will be encouraged to work together towards genuine truth and justice. On the other hand, if the result in this case -- on an issue that is obviously one of enormous and timely public health import -- is to set the standard, then future litigants and scientists[5] will be very loathe to proceed in this fashion.

The Millers heeded Justice Breyer's advice. It was not Pfizer who asked the court to appoint independent experts. It was the Millers themselves. Pfizer went along, kicking and screaming, *i.e.*, the experts were appointed over Pfizer's objections. But a procedure which should have been scientifically rigorous became legally turgid. The experts did not "neutrally" focus on both sides experts or scientific issues which they themselves found significant. Rather, Pfizer set the agenda through its *Daubert* motion and the Court then restricted the scope of inquiry and information which the experts could consider. Rule 26 trumped Rule 703, and the experts' scientific questions, even as to those points, were unanswered. Moreover, the real point of methodological criticism, *i.e.*, whether Dr. Healy's "relative risk" calculations could be replicated, focused on a Pfizer contention which both the independent experts and the court below found to be misguided. Sadly, in the end, the Millers were hoisted on their own petard, and the memory of their only son's life was sacrificed on the altar of Pfizer's profits and judicial expediency.

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[5] The independent experts in this case were not told what the ramifications of their opinions would be. Only later did they learn that their scientific critique and comments resulted in the exclusion of testimony from a highly qualified colleague and the deprivation of a day in court for the Miller family. One can only imagine how mortified they must have been on March 22, 2004, when the FDA itself ruled that Pfizer should warn about this very side effect. App. 5-6.

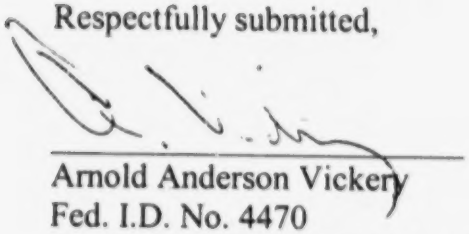
CONCLUSION

Other parents who have lost a child to SSRI-induced violence have had their day in court. And they had it with benefit of the expert testimony of Dr. Healy. Tim Tobin was awarded $2 million as a result of the SSRI-precipitated death of his daughter Alyssa. *Tobin v. SmithKline Beecham Pharms., supra.* If Pfizer follows the FDA's March 22, 2004 recommendation, parents in the future will also be forewarned about the potential of Zoloft to cause their teenagers to take their own lives. App. 5-6. This will save lives.

But in the meantime, what is to become of Mark and Cheryl Miller and their quest for justice? What will the Highest Court in the Land say to them? Too bad? Too late? Tough stuff? OR, will the Court find that justice is far too precious a commodity to be relegated to "gotcha" status?

For the foregoing reasons, we urge the Court to grant *certiorari* in this case and consider the case upon its full merits and in light of the most current and authoritative information available to date. As an alternative, and particularly in light of the FDA's recent awakening, the Court could GVR the case as it did in *Lawrence, supra,* and remand with instructions that the district court should reconsider its *Daubert* decision in light of all information currently available at the time that the court rules.

Respectfully submitted,



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PROOF OF SERVICE
CERTIFICATE OF SERVICE

Pursuant to Rule 29.3 of the Rules of the Supreme Court of the United States, I certify that three copies of the Petition for Writ of Certiorari have been served upon counsel named below via certified mail, return receipt requested, on this 30th day of April, 2004:

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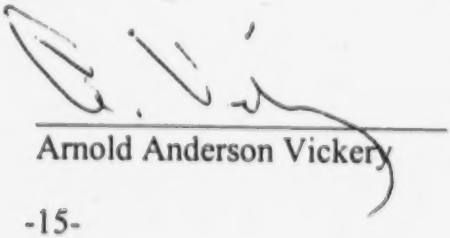

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